



DEPARTMENT OF HEALTH & HUMAN SERVICES

Purged
Public Health Service

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JAN 16 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Eugen Martin
General Manager
S. u. A. Martin GmbH & Co.
Unhlandstrasse 19
D-78604 Rietheim-Weilheim
Tuttlingen, Germany

Dear Mr. Martin:

During an inspection of your firm located in Tuttlingen, Germany, on November 22 and 25, 1996, our investigator determined that your firm manufactures surgical instruments. Surgical instruments are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and implement specification control measures to assure that the design basis for the devices and packaging is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). For example, the in-house passivation process has not been validated to assure the absence of rust and corrosion on the surgical instruments.
2. Failure to have specification changes approved and documented by a designated individual(s), including an approval date and the date the change becomes effective, as required by 21 CFR 820.100(a)(2). For example:
 - a. The reason for changes made to the CNC software programs was not documented nor signed off by a designated individual.

- b. When the CNC software is changed, the previous versions are overwritten or lost, thus making traceability of the software's evolution impossible.
- 3. Failure to have written procedures describing any processing controls necessary to assure conformance to specifications, where deviations from device specifications could occur as a result of the manufacturing process itself, as required by 21 CFR 820.100(b)(1). For example:
 - a. There are no changing interval procedures for the ultrasonic bath solution, where an excessively dirty solution can decrease the cleaning effect and increase the risk of corrosion on the instruments.
 - b. There are no changing interval procedures for the passivation chemicals, where variations in the solution concentration over time or excessive dirt and contaminants in the solution can destroy the coating on the instruments or affect long-term rust protection.
- 4. Failure to conduct processing control operations in a manner designed to assure that the device conforms to applicable specifications, as required by 21 CFR 820.100(b)(2). For example, the software program number and CNC machine identification were not recorded in the appropriate spaces on the instrument records.
- 5. Failure to establish adequate written procedures for finished device inspection, including a sampling plan for checking, testing, and release of devices based on an acceptable statistical rationale, as required by 21 CFR 820.160. For example, there is no boil test sampling plan to assure the adequacy of the passivation process.
- 6. Failure to adequately investigate any failure of a device to meet performance specifications after a device has been released for distribution, as required by 21 CFR 820.162. For example, defective product returns due to rust spots were not investigated to determine the cause of the imperfections and to determine corrective actions.
- 7. Failure of the device master record to include production process specifications including appropriate equipment specifications, production methods, production procedures, and production environment specifications,

as required by 21 CFR 820.181(b). For example, specification ranges for the X, Y, and Z dimensions in the CNC machine software for each instrument have not been defined in the device master record.

8. Failure to maintain a device history record adequate to demonstrate that each device is manufactured in accordance with the device master record, including any control numbers used, as required by 21 CFR 820.184. For example:
 - a. There is no boil test record maintained to assure the adequacy of the passivation process in preventing rust on the instruments.
 - b. The software program number and CNC machine identification were not recorded in the appropriate spaces on the instrument records in the device history records.
 - c. The quantity and reason for rejection of certain surgical instruments during the milling process were not documented.
9. Failure to develop and adhere to a written schedule for maintenance, adjustment, and cleaning of equipment, and to maintain written records documenting the performance of scheduled maintenance activities, to assure that manufacturing specifications are met, as required by 21 CFR 820.60(a). For example:
 - a. There is no maintenance schedule for changing the ultrasonic bath solution nor records kept.
 - b. There is no maintenance schedule for changing the passivation solution nor records kept.
10. Failure to have written procedures for acceptance of components and inspecting, sampling, and testing components for conformance to specifications, and failure to inspect for conformance, where deviations from component specifications could result in the device being unfit for its intended use, as required by 21 CFR 820.80(a). For example:
 - a. Copies of steel certifications from the forging suppliers to assure the quality of the metal are not requested nor maintained.

- b. Specific inspection criteria for Type 1 and Type 2 rejections of the incoming forgings have not been defined.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance programs. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be systemic problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

Given the serious nature of these violations of the Act, all devices manufactured by S. u. A. Martin, GmbH, Unhlandstrasse 19, D-78604 Rietheim-Weilheim, Tuttlingen, Germany may be detained upon entry into the United States until these violations are corrected.

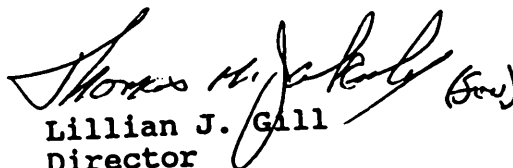
In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the responses are adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

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Your response should be sent to: General Surgery Devices Branch (HFZ-323), Division of Enforcement I, Office of Compliance, Center for Devices and Radiological Health, FDA, 2098 Gaither Road, Rockville, Maryland 20850 USA. If you have further questions on these requirements, please contact Ms. Cory Tylka of the General Surgery Devices Branch at phone: (301) 594-4595, or FAX: (301) 594-4636.

Sincerely yours,

 (Sv)

Lillian J. Gall
Director
Office of Compliance
Center for Devices and
Radiological Health

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